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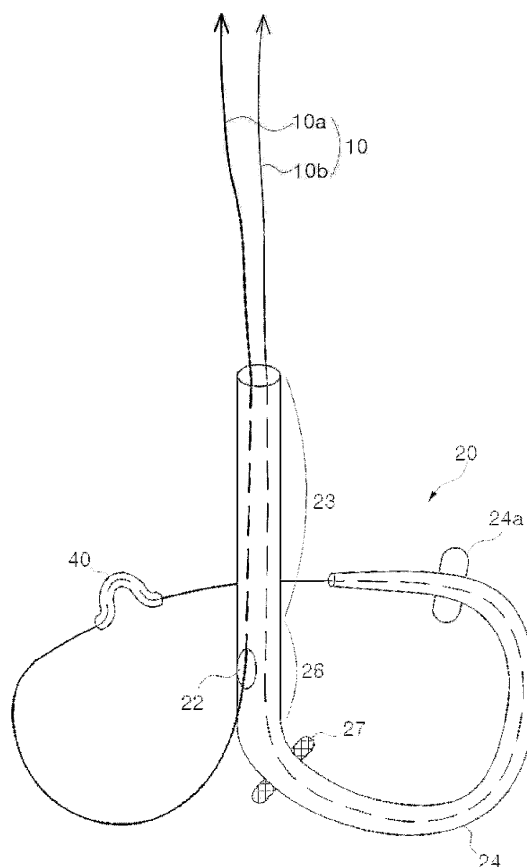
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(54) **TISSUE PROTECTION DEVICE FOR MITRAL VALVE MEMBRANE CERCLAGE PROCEDURE**

(57) The present invention relates to a tissue protection device for mitral valve cerclage annuloplasty and, more particularly to a tissue protection device for protecting tissues of the body (heart) during mitral valve cerclage annuloplasty that is performed on a mitral valve cerclage patient with mitral regurgitation. The tissue protection device for mitral valve cerclage annuloplasty of the present invention is a hollow cylindrical tube where cerclage sutures (10a, 10b) are inserted, in which a hole (22) is formed at a predetermined portion of the cylindrical tube so that a coronary sinus cerclage suture (10a) inserted in a coronary sinus comes out of the cylindrical tube, and a lower section from the hole is inserted into the tricuspid valve to protect tissues of the tricuspid valve and the ventricular septum.

FIG. 1



Description

Technical Field

[0001] The present invention relates to a tissue protection device for mitral valve cerclage annuloplasty and, more particularly to a tissue protection device for protecting tissues of a body (heart) during mitral valve cerclage annuloplasty that is performed on a mitral valve cerclage patient with mitral regurgitation.

Background Art

[0002] The heart is the center of the human circulatory system that pumps blood through our body. It is a muscle that pumps the blood only in one direction. In order for the heart to effectively maintain this unidirectional flow of blood, it must have properly functioning valves that prevent back flow through its system, or regurgitation. The heart is divided into four chambers: right and left atrium, and right and left ventricles. The four chambers are connected to the aorta, inferior and superior vena cava, pulmonary artery, and pulmonary veins.

[0003] The mitral valve (MV) separates left atrium from left ventricle while the tricuspid valve (TV) separates right atrium from the right ventricle. The aortic valve (AV) is located between the left ventricle and the aorta while the pulmonary valve (PV) is located between the right ventricle and the pulmonary artery.

[0004] Generally, valves should open and close completely with every heart beat or contraction. Incomplete opening or closing of the valves causes improper flow of blood. Valvular diseases are divided into two categories, regurgitation and stenosis. Regurgitation is a failure of a valve to close completely and stenosis is a failure of a valve to open completely.

[0005] Mitral valve regurgitation (MVR) is a common cardiac valve disorder that is caused by incomplete closure of the mitral valve (MV). The MV is located between the left atrium and the left ventricle. Over time, MVR places a burden on the heart and worsens its ability to pump blood properly. Such stress on the heart will ultimately lead to heart failure.

[0006] Traditional treatment for worsening MVR requires open heart surgery with sternotomy or thoracotomy with cardiac arrest and cardio-pulmonary bypass. Once the chest is open and access to heart is gained, the MV is either repaired or replaced using an artificial valve. Although very effective, this open-heart procedure is a high risk surgery accompanied by substantial morbidity and prolonged convalescence. Mortality due to surgery itself can be as high as 5%. As a result, the procedure often is not offered to patients who are insufficiently symptomatic to justify the surgical risk and morbidity, or to patients with substantial co-morbidity. It is reserved only for those with severe symptomatic MVR. This high morbidity rate of open heart surgery has motivated further research into developing a safer and less risky alternative

to repair MV. Much of the research involves use of cardiac catheterization. Recently, the inventor of the present invention presented a thesis regarding "mitral valve cerclage coronary sinus annuloplasty (MVA)" showing outstanding results of MVR treatment through applying circular pressure around the mitral annulus (MA). This thesis has been filed through PCT as an international patent application (PCT application number PCT/US2007/023836) and has been published (International publication number WO2008/060553).

[0007] The aforementioned thesis and published patent application disclosed the mitral cerclage coronary annuloplasty (MVA) procedure. Briefly explained, a catheter is placed in coronary sinus after accessing the right atrium through the jugular vein, and then a cerclage suture is passed through the proximal septal vein. This cerclage suture can easily pass through right ventricular outflow tract (RVOT), and this inventor defines this technique as "simple mitral cerclage annuloplasty". Then, the cerclage suture can be easily pulled into the right atrium thus placing the cerclage suture circumferentially around the mitral annulus. Once positioned, tension is applied to the cerclage suture, thereby tightening the mitral valve. This brings together the two lobes of the MV so that they are approximated and reduce the size of its incomplete closure. This procedure can theoretically obtain very similar results to those that conventional surgeries can obtain by directly tightening the mitral annulus, and shows an immediate reduction of MVR.

[0008] However, the cerclage suture passes through the tricuspid valve and the heart, so it may reduce the function of the valve or may damage the valve and other parts. The inventor has developed a tissue protection device for the coronary sinus and the tricuspid valve and has filed a patent application as a technology for protecting tissues in a body (heart) and it has been registered (Korean Patent No. 10-1116867, registered on February 08, 2012).

Disclosure

Technical Problem

[0009] The present invention is proposed to improve the technology disclosed in Korean Patent No. 10-1116867 of the inventor and provides a tissue protection device for mitral valve cerclage annuloplasty, whereby the device can protect tissues in the body from a cerclage suture having a simpler structure than the suture used in cerclage annuloplasty.

Technical Solution

[0010] In order to achieve the object of the present invention, a tissue protection device for mitral valve cerclage annuloplasty of the present invention is a hollow cylindrical tube where cerclage sutures 10a and 10b are inserted, in which a hole 22 is formed at a predetermined

portion of the cylindrical tube so that a coronary sinus cerclage suture 10a inserted in a coronary sinus comes out of the cylindrical tube, and a lower section from the hole is inserted into a tricuspid valve to protect tissues of the tricuspid valve and a ventricular septum.

[0011] The cylindrical tube may have: a stem section 23 at an upper portion; a support section 26 connected to the stem section, having the hole, defined at a predetermined portion over and under the hole, and being more rigid than a tricuspid valve insert; and a tricuspid valve insert 24 connected to the support section and protecting tissues of the tricuspid valve and the ventricular septum. The tube may be thicker at the support section than at the tricuspid valve insert.

[0012] A protrusion 27 may be formed at a predetermined portion of the cylindrical tube to inform a user of the position of the coronary sinus.

[0013] The coronary sinus cerclage suture 10a and the tricuspid valve cerclage suture 10b may be connected to each other, and the coronary sinus cerclage suture 10a may be formed to be more rigid than the tricuspid valve cerclage suture 10b.

[0014] A stopper 24a preventing the cylindrical tube from going deep inside the myocardium may be formed at a lower end portion of the cylindrical tube, and the stopper 24a may be a circular protrusion.

[0015] The device may become narrower as it goes to an end to cover a cerclage suture in the ventricular septum.

Advantageous Effects

[0016] As described above, the tissue protection device for mitral valve cerclage annuloplasty of the present invention has a simple structure for protecting the body in mitral valve cerclage annuloplasty performed on a patient with mitral regurgitation, so it is possible to provide convenience and safety in annuloplasty.

Description of Drawings

[0017]

Fig. 1 is a schematic perspective view of the tissue protection device for mitral valve cerclage annuloplasty according to an embodiment of the present invention.

Fig. 2 is a virtual partial cut view of a heart with the tissue protection device for mitral valve cerclage annuloplasty according to an embodiment of the present invention.

Fig. 3 is a partial cross-sectional view of the tissue protection device for mitral valve cerclage annuloplasty according to an embodiment of the present invention.

Best Mode

[0018] Hereinafter, the tissue protection device for mitral valve cerclage annuloplasty of the present invention will be described in detail with reference to the accompanying drawings.

[0019] Fig. 1 is a schematic perspective view of the tissue protection device for mitral valve cerclage annuloplasty according to an embodiment of the present invention and Fig. 2 is a virtual partial cut view of a heart with the tissue protection device for mitral valve cerclage annuloplasty according to an embodiment of the present invention.

[0020] A cerclage suture 10, which is a very thin thread having a thickness of about 0.014" and used for mitral cerclage coronary sinus annuloplasty (MVA), was named in the meaning that a piece of string comes out of a body after going around a coronary sinus (CS), a tricuspid valve (TV), and a ventricular septum, and when the cerclage suture comes out of a body, it is divided into two pieces at one end and the other end. That is, a cerclage suture is divided into a coronary sinus cerclage suture 10a and a tricuspid valve cerclage suture 10b in Fig. 1, but it is one continuous string making a circle, as shown in the figure. The cerclage suture may be a string made of synthetic resin such as nylon or a metallic wire (stainless steel or metal coated with nylon). Further, a wire formed by twisting a plurality of thin wires may be used. When the cerclage suture 10 is made by twisting a plurality of strings (wires), it is also called a "cerclage rope" or a "cerclage wire" and it is also a kind of cerclage suture.

[0021] A tissue protection device 20 is a hollow cylindrical tube where the cerclage sutures 10a and 10b are inserted. The tissue protection device 20 is a hollow cylindrical tube, that is, it has an empty inside and is manufactured as thick as a 4Fr catheter. The material is a soft and flexible rubber or synthetic resin. Alternatively, a metal spring coated with biological synthetic resin may be used.

[0022] As for each part of the tissue protection device 20, the device is composed of a stem section 23 that is the upper part, a support section 26 that is the middle part, and a tricuspid valve insert 24 that is the lower part. The parts collectively make one hollow thin cylindrical tube.

[0023] The tissue protection device of the present invention has a hole 22 at a predetermined position and the hole 22 is a part through which the coronary sinus cerclage suture 10a inserted in a coronary sinus comes out of the cylindrical tube. The support section 26 is defined to predetermined positions over and under the hole 22, the step section 23 is defined over the support section, and the tricuspid valve insert 24 for protecting a tricuspid valve and a ventricular septum is defined under the support section.

[0024] The coronary sinus cerclage suture 10a and the tricuspid valve cerclage suture 10b are connected to

each other. The cerclage suture 10a that is supposed to be inserted into a coronary sinus is not covered with the tube in the coronary sinus, so it may be formed to be more rigid than the tricuspid valve cerclage suture 10b in order to protect the coronary sinus tissues. The coronary sinus cerclage suture 10a is formed thicker than the tricuspid valve cerclage suture 10b and thus damage to the coronary sinus tissues due to the coronary sinus cerclage suture is prevented.

[0025] The support section 26 where the hole 22 for the coronary sinus cerclage suture 10a to come out of the tissue protection device 20 is connected to the stem section 23 and positioned under the stem section 23.

[0026] The support section 26 is formed to be more rigid than the stem section 23 or the tricuspid valve insert 24. This is for more stably supporting the coronary sinus cerclage suture 10a when the coronary sinus cerclage suture 10a comes out of the hole.

[0027] Fig. 3 is a partial cross-sectional view of a tissue protection device for mitral valve cerclage annuloplasty according to an embodiment of the present invention.

[0028] As shown in Fig. 3, the support section 26 is thicker than the tricuspid valve insert 24. That is, since it is preferable that the support section 26 is more rigid than the tricuspid valve insert 24, the tube is formed thicker at the support section 26 than at the tricuspid valve insert 24. In order to make the support section rigid, the outer diameter of the support section may be increased or the support section may be made of a different material.

[0029] The tricuspid valve insert 24 connected to the support section 26 is a part that protects the tricuspid valve and the ventricular septum from the cerclage suture 10b that is inserted in the tricuspid valve.

[0030] A stopper 24a is formed at a lower end portion of the cylindrical tube (that is, a lower end portion of the tricuspid valve insert) to prevent the tissue protection device from going deep inside the myocardium. The stopper 24a may be a circular protrusion, as shown in the figure. Further, as shown in the figure, the lower end portion of the cylindrical tube (that is, the lower end portion of the tricuspid valve insert) may become narrower as it goes to the end in order to cover the cerclage suture 10b in a ventricular septum.

[0031] The distance between an RVOT stopper 24a and the hole 22a is selected in advance such that the tricuspid valve insert 24 is around two times longer than the distance between an RVOT exit and the coronary sinus hole that is measured from a scanning image of a patient obtained in advance. That is, the distance between the hole 22 and the stopper 24a is designed around two times longer than the distance from the stopper to the end. To this end, it may be possible to change the position of the stopper at the tricuspid valve insert 24, but various tissue protection devices having different distances between the hole 22 and the stopper 24a may be provided.

[0032] When the coronary sinus cerclage suture 10a coming out of the tissue protection device 20 is inserted

into the coronary sinus, the hole 22 is locked to the edge of a CS inlet. Accordingly, the stopper 24a of the tricuspid valve insert 24 (RVOT exit stopper) and the hole 22 are fixed, so the tricuspid valve insert 24 is curved into a reverse C-shape as long as the length without being in contact with the wall of the tricuspid valve (TV). Accordingly, erosion of the tricuspid valve due to the cerclage suture 10 is prevented and movement of lobes of the mitral valve is less limited.

[0033] On the other hand, a protrusion 27 may be formed on the outer side of the tissue protection device 20, as shown in the figure. The protrusion 27 prevents the tissue protection device from being excessively inserting into the body by locking to a tissue inside the body and supports a side when the tricuspid valve insert 24 is curved in a reverse C-shape.

[0034] The embodiments described above are just examples of the present invention and the scope of the present invention is not limited to the embodiments. The present invention may be changed, replaced, and modified in various ways by those skilled in the art without departing from the scope of the present invention described in claims.

Industrial Applicability

[0035] The present invention can be used for a tissue protection device for mitral valve cerclage annuloplasty and, more particularly to a tissue protection device for protecting tissues of the body (heart) during mitral valve cerclage annuloplasty that is performed on a mitral valve cerclage patient with mitral regurgitation.

Claims

1. A tissue protection device for mitral valve cerclage annuloplasty, the tissue protection device being a hollow cylindrical tube where cerclage sutures (10a, 10b) are inserted, wherein a hole (22) is formed at a predetermined portion of the cylindrical tube so that a coronary sinus cerclage suture (10a) inserted in a coronary sinus comes out of the cylindrical tube, and a lower section from the hole is inserted into a tricuspid valve to protect tissues of the tricuspid valve and a ventricular septum.
2. The device of claim 1, wherein the cylindrical tube has: a stem section (23) at an upper portion; a support section (26) connected to the stem section, having the hole, defined at a predetermined portion over and under the hole, and being more rigid than a tricuspid valve insert; and a tricuspid valve insert (24) connected to the support section and protecting tissues of a tricuspid valve and a ventricular septum.
3. The device of claim 2, wherein the tube is thicker at the support section than at the tricuspid valve insert.

4. The device of claim 1, wherein a protrusion (27) is formed at a predetermined portion of the cylindrical tube to inform a user of the position of a coronary sinus.
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5. The device of claim 1, wherein the coronary sinus cerclage suture (10a) and the tricuspid valve cerclage suture (10b) are connected to each other, and the coronary sinus cerclage suture (10a) is formed to be more rigid than the tricuspid valve cerclage suture (10b).
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6. The device of claim 1, wherein a stopper (24a) preventing the cylindrical tube from going deep inside a myocardium is formed at a lower end portion of the cylindrical tube.
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7. The device of claim 6, wherein the stopper (24a) is a circular protrusion.
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8. The device of claim 1, wherein the device becomes narrower as it goes to an end to cover a cerclage suture in a ventricular septum.
9. The device of claim 6, wherein the device maintains a reverse C-shape between the hole and the stopper without being in contact with a wall of a tricuspid valve in cerclage annuloplasty.
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FIG.1

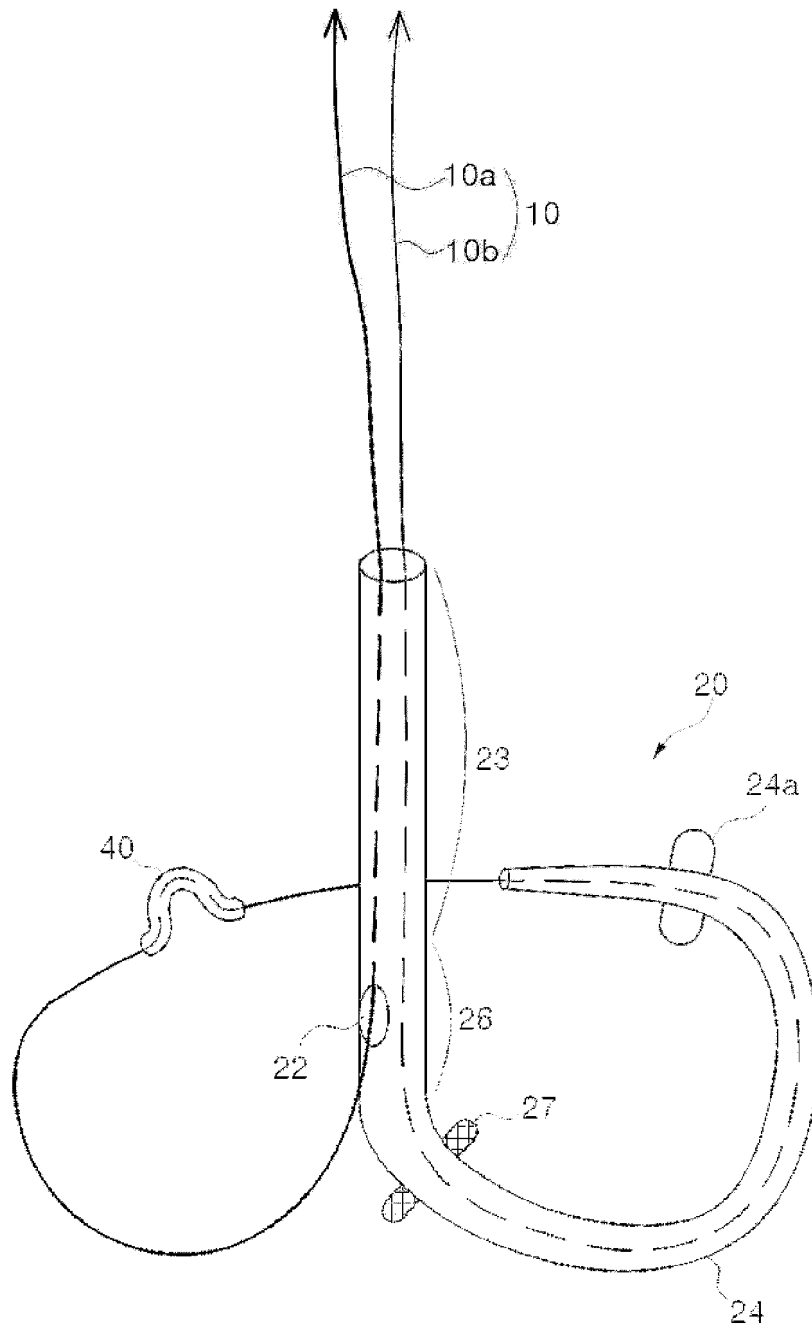


FIG.2

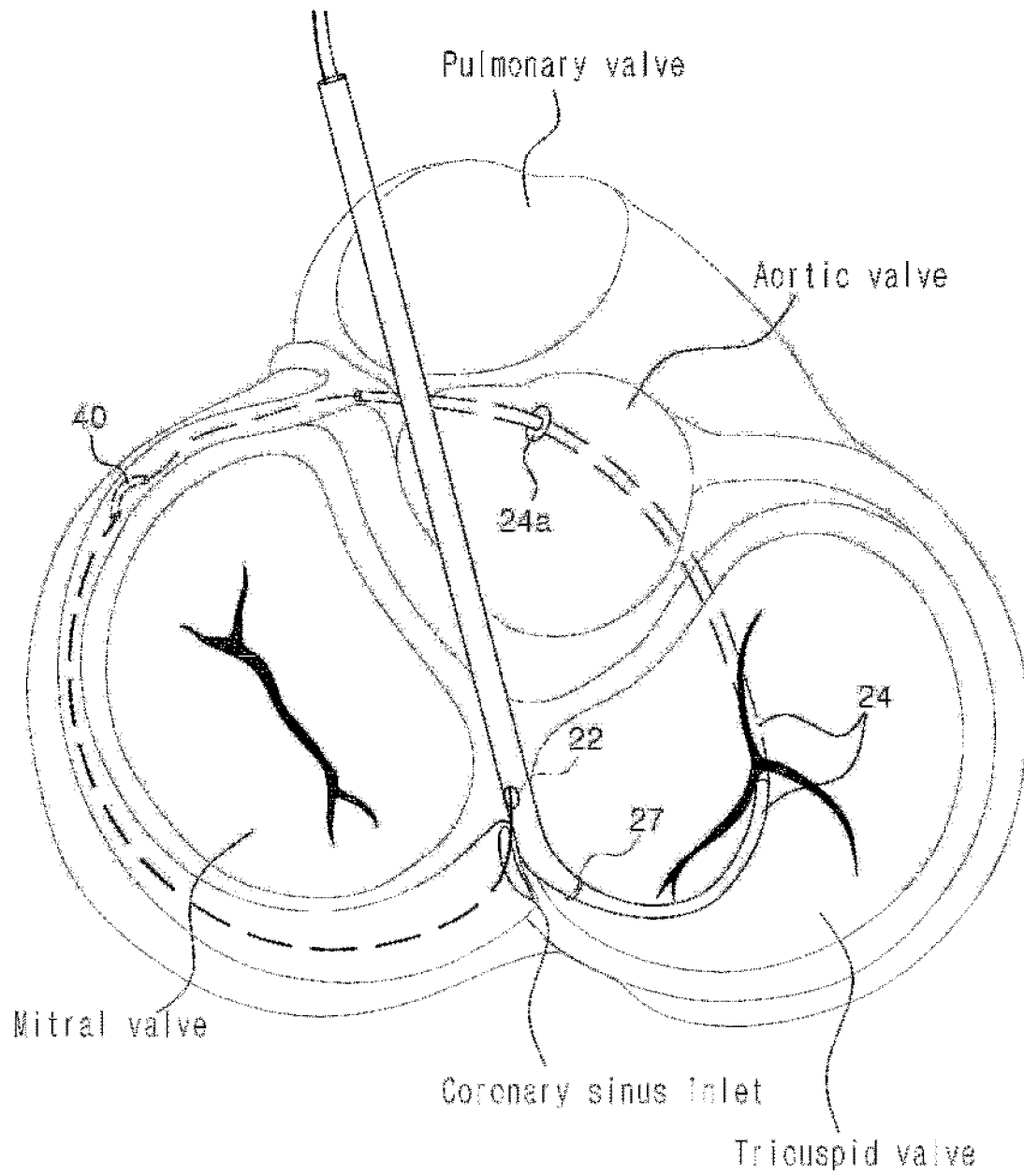
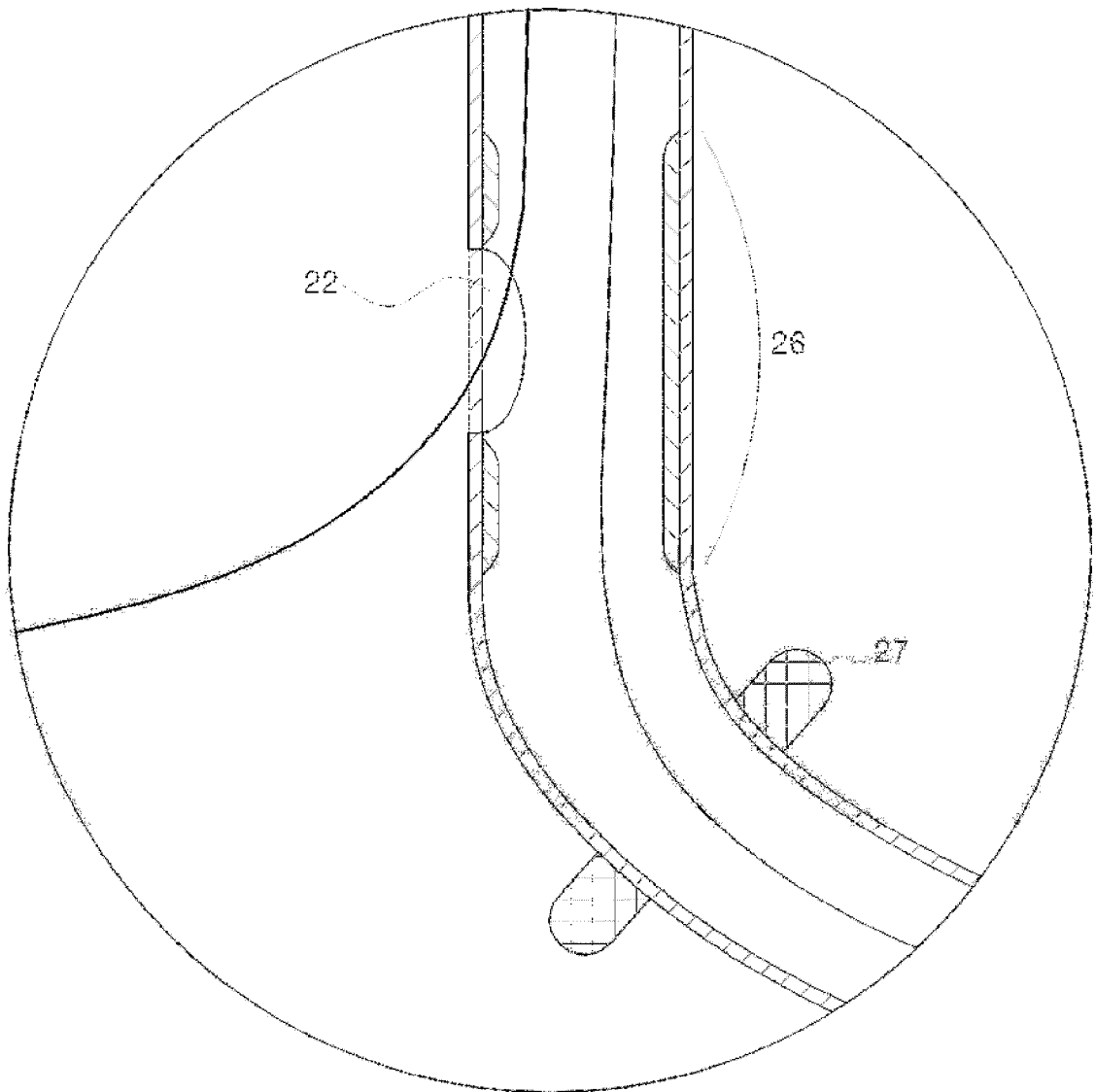


FIG.3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/KR2015/004728

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/00(2006.01)i, A61B 19/00(2006.01)i, A61F 2/24(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/00; A61F 2/24; A61M 25/09; A61F 2/06; A61F 2/04; A61B 17/04; A61B 19/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean Utility models and applications for Utility models: IPC as above

Japanese Utility models and applications for Utility models: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS (KIPO internal) & Keywords: mitral cerclage surgical procedure, tissue, protection, cylindrical tube, hole, suture

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KR 10-1116867 B1 (KIM, June - Hong) 06 March 2012 See paragraphs [0011]-[0058]; claims 1-17; and figures 1-6.	1-9
A	WO 2008-060553 A1 (THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.) 22 May 2008 See pages 4-29; claims 11-24; and figures 1A-10.	1-9
A	US 6402781 B1 (LANGBERG, Jonathan J. et al.) 11 June 2002 See column 3, line 51-column 13, line 52; claims 1-32; and figures 1-9.	1-9
A	KR 10-1296604 B1 (PUSAN NATIONAL UNIVERSITY INDUSTRY-UNIVERSITY COOPERATION FOUNDATION et al.) 14 August 2013 See paragraphs [0013]-[0053]; claims 1-4; and figures 1-4.	1-9
A	US 2008-0228201 A1 (ZARBATANY, David et al.) 18 September 2008 See paragraphs [0010]-[0092]; and figures 1-44.	1-9

☐ Further documents are listed in the continuation of Box C.
 ☒ See patent family annex.

* Special categories of cited documents:	"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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